FOOD SAFETY IN FOOD SECURITY AND FOOD TRADE

Food Safety and GM Crops: Implications for Developing-Country Research

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2020 VISION FOR FOOD, AGRICULTURE, AND THE ENVIRONMENT

FOCUS 10 • BRIEF 16 OF 17 • SEPTEMBER 2003

In the developing world the approval and cultivation of genetically modified (GM) crops is largely limited to the commercial production of insect-resistant cotton in Argentina, China, India, Mexico, and South Africa. Approvals of GM crops used for food or feed lag far behind cotton: a single transgenic maize event (an instance of genetic modification) has been approved in the Philippines and South Africa, and a single transgenic soybean event has been approved in Argentina, Mexico, South Africa, and Uruguay. Argentina has also approved six GM corn events for cultivation. In contrast, 11 food and feed crops representing over 47 transgenic events have been approved for cultivation in the developed world.

This gap in approvals is unfortunate, because crop biotechnology, appropriately applied, has the potential to address key production constraints affecting resource-poor farmers. Currently, important public- and private-sector research is underway to help meet the productivity needs of these farmers. This research is built on the transformation of local crop germplasm and the expression of locally important traits. The work involves national research programs in developing countries and international centers. To date, over 50 crops have been transformed in 16 developing countries, incorporating a wide range of genes for insect, fungal, viral, and bacteria resistance; protein and quality improvements; herbicide tolerance; and salt and drought stress.

However, the value of these novel crops will be realized only after they are approved for cultivation by national regulatory authorities. Obtaining environmental and food safety approval is difficult though, given current institutional capacities, technological capabilities, and political decisions regarding regulation in developing countries. In fact, the approval process, while addressing safety concerns, can also be a significant constraint to introducing GM seeds in the developing world. Many countries, such as Zambia and Zimbabwe, also maintain GM-free policies to certify and protect domestic food markets and beef exports to Europe.

Over and above having to increase regulatory capacity, developing countries face competing regulatory paradigms in the developed world. Although governments have reached relatively clear agreement on the scientific principles of food safety assessment, they have not reached consensus on the extent of data required to comply with these principles or on the role of data in overall decisionmaking. As a result, developing countries face the following questions: What information will assure developed countries that they are importing safe food? How and by whom should this information be generated? And how should it be shared for maximum advantage? Furthermore, developing countries will have to assess how their exports will be affected if developed countries require labeling of GM foods. In approving GM crops, developing countries evaluate not only how GM seeds impact agricultural productivity, but also how GM products influence their participation in global trade.

FOOD SAFETY IN GM CROPS

Plant breeders have continuously introduced new crops, genes, and traits into our diet and farming communities with few food and feed safety problems. We know, however, that some traditionally developed foods that contain allergenic proteins can cause mild to severe reactions from milk, shellfish, soya, peanuts, wheat, tree nuts, and eggs. Furthermore, traditional breeding of products such as potatoes can cause elevated amounts of endogenous toxicants such as glycoalkaloids. By comparison, no approved biotechnology product has been found to produce allergic or toxic reactions.

However, concerns with genetically engineered crops persist partially because of the perception that gaining access to a wider range of genetic diversity, crossing species barriers, and introducing foods with additional proteins present safety concerns via our diets. The main source of worry is the potential for allergic reactions. One example of allergenic concerns arose in the summer of 2000, when traces of StarLink™ corn were detected in some food products, such as taco shells. StarLink™ was approved for use in animal feed, but not for human consumption. Approval for human consumption was withheld because the Bt Cry9c protein in corn did not disappear as quickly as other Bt proteins in test assays. The unintentional commingling of StarLink™ with corn in the food chain led to concerns about food safety. The U.S. Food and Drug Administration (FDA) developed a method to detect the antibody indicating hypersensitivity to the Cry9c protein. The FDA evaluated the actual case samples against reference samples. It sent the data to the Centers for Disease Control, which compared case values with control values. These studies found no allergenic reactions associated with Cry9c.

REGULATORY APPROACHES TO FOOD SAFETY FOR GM FOODS

The Organisation for Economic Co-operation and Development (OECD) defines food safety as "reasonable certainty that no harm will result from intended uses under anticipated conditions of consumption." To arrive at reasonable certainty, the OECD uses the concept of substantial equivalence (as developed by the World Health Organization, the OECD, and the Food and Agriculture Organization of the United Nations), because conventional toxicology cannot adequately evaluate novel foods. Substantial equivalence "embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new." The concept also serves as the premise for work

based on the Codex Alimentarius, which has become the seminal global reference point for consumers, food producers and processors, national food control agencies, and international food trade.

Substantial equivalence offers a science-based approach for comparing genetically modified foods with an existing or conventionally bred counterpart. Providing clear analysis of differences and similarities between these foods can help structure a safety assessment, but by itself, substantial equivalence is not a safety assessment. This concept has been the target of criticism, as some believe it does not provide enough information to determine safety.

Data that help determine or explain similarities and differences between GM and traditional foods come largely from molecular and protein characterization, which, some propose, can involve testing to determine gene expression patterns, protein profiling, changes in protein expression, and differences in metabolic capabilities. One difficulty in utilizing this information is that the biological significance and safety implications of the data may not be established.

The application of characterization and feeding methodologies also presents problems. Standards used in the U.S. or Europe to determine food safety present significant difficulties in the developing world. Even though food safety data generated by one country can be submitted and accepted in another, countries may not be aware of data generated elsewhere. Countries may also seek additional feeding trials or molecular studies over and above commonly required tests. If generation of additional data requires sophisticated technologies, as is the case for protein profiling, then developing countries will be strained to comply with food safety standards. Developing countries themselves have called for additional animal feeding studies, to assure those concerned about the safety of animals that may consume GM products in the field.

Food safety assessments are essential to GM approvals and, as such, need to be started early in the process of GM crop development. Commercial providers of GM crops often complete food safety assessments with seed or other material harvested from confined trials (that is, before committing to extensive seed production). For developing countries, such a sequence in GM crop development may be problematic, because they may have few laboratories and scientists capable of food safety testing, may lack information on the tests or data required, and may not have fully anticipated funding needs. In addition, it is often difficult to obtain approval for multilocation, confined field trials, and yet these trials are needed by scientists to obtain material for safety evaluations. For these reasons, food safety testing, including generation of data and regulatory review, has become one of several problematic issues in the regulation of GM crops.

While the proponent of a given GM event is expected to test for safety (rather than a regulatory agency), a competent regulatory authority needs to review the data. However, it is for each developing country to determine how, when, and to what extent regulatory agencies themselves will be involved in testing. The challenge of assuring safety becomes more complicated as the range of GM products expands and the chance that a substantial comparator crop exists decreases. Difficulty in reaching international agreement on food safety standards and scientific uncertainty about how to evaluate safety, coupled with the lack of a clear, "one-window" approach for regulation in developing countries, means that developed and developing countries lack a clear, uniformly accepted path to regulatory approval of GM foods.

WHAT DOES THE FUTURE HOLD?

It is often stated that GM products pose no new food safety risks when compared to traditionally produced foods, and to date, no safety problems have been identified for GM products approved for use. Most GM products are considered substantially equivalent to traditional counterparts, with exceptions for certain well-defined differences. Safety evaluations focus on these defined differences. For developing countries, the need to make such assessments raises questions about who will generate the data; which approach will be followed (substantial equivalence or some other); and what degree of uncertainty about food safety developing countries will permit?

The present atmosphere surrounding genetically engineered crops has led to a situation where food safety assessment is not just about science, but also about perceptions, concerns, and standards about how to assure "safety." As scientific opportunities advance, agreement on reasonable standards of safety for developing countries will be critical. This will also allow for and encourage exchange of data, which will help ensure that data requirements are manageable not only among OECD countries, but across the developing world as well. As part of capacity building for biotechnology and biosafety, competency in assuring food safety for GM crops is essential. This competency will enable countries to conduct independent research when necessary. Building such capacity also creates sufficient infrastructure to allow scientifically defensible decisions in the face of food safety questions colored by each country's perceptions and circumstances. ■

For further reading see K.T. Atherton, *Genetically Modified Crops – Assessing Safety* (London: Taylor and Francis, 2002) and *Safety Aspects of Genetically Modified Foods of Plant Origin*, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (Geneva: WHO, 2000).

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